

GlaxoWellcome

February 14, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: NAS; Not Product Specific

General Correspondence: Other

Docket No. 99N-1852:21 CFR Parts 314 and 601: Proposed Rule: Postmarketing Studies for Human Drugs and Licensed Biological Products; Status Reports

Dear Sir/Madam:

Glaxo Wellcome endorses publication of the above Proposed Rule in the Federal Register on December 1, 1999. We do have some comments on the Proposed Rule and these are listed in the attached document. Each suggestion is cross-referenced to the relevant section of the Federal Register publication and preceded by a bolded summary of the text to which the comment pertains.

For your convenience, a non-archivable electronic copy of these comments (Word '97) is enclosed on diskette. Please contact me on (919) 483-4483 or my colleague Nasser Hassan on (919) 483-9066 with any questions or request for clarification. Thank you for your consideration of our comments.

Sincerely,



Alison Bowers
Product Director
Regulatory Affairs

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Glaxo Wellcome Research and Development

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A Division of
Glaxo Wellcome Inc.

Federal Register December 1, 1999 - Proposed Rule: Postmarketing Studies for Human Drugs and Licensed Biological Products; Status Reports

E. Report Submission Requirements

A status report under proposed Secs. 314.81(b)(2)(vii) and 601.70 should be submitted to FDA until the agency notifies the applicant, in writing, that the study commitment has been fulfilled or acknowledges that the study is either no longer feasible or would no longer provide useful information. Applicants would be required to submit a final study report to FDA and continue to submit status reports for the study until the agency evaluates the final study report and concurs, in writing, with the applicant's determination.

We suggest that FDA's confirmation in writing that a study commitment has been fulfilled could reasonably be accommodated through addition of a suitable field in the Form 2252 which would be completed by FDA at the time that receipt of the Annual Report is acknowledged. From that point on, the status of the postmarketing commitment would be tracked under Outstanding Regulatory Business.

This suggestion, intended to reduce the administrative burden on FDA of acknowledging receipt of final study reports, would not remove the need for FDA to confirm in writing that they have evaluated the study report and concur with the applicant's conclusions or proposed action, e.g., submission and approval of a labeling supplement to accommodate study results.

F. Public Disclosure of Information

For drugs and biologics with approved NDA's, ANDA's, and BLA's, FDA intends to fulfill its annual reporting requirement mandated by section 506B(c) of the act by publishing in the Federal Register, the status of postmarketing study commitments reported under proposed Secs. 314.81(b)(2)(vii) and 601.70.

We wish to confirm that this disclosure will only apply to the Status Report described in Section C. and not to the Log of Outstanding Regulatory Business described in Section D.

G. Proposed Implementation Scheme

Applicants that have entered into a commitment prior to November 21, 1997, to conduct a postmarketing study described under proposed Sec. 314.81(b)(2)(vii) or

proposed Sec. 601.70 would be required to submit an initial report to FDA within 6 months after the effective date of the final rule. Thus, in some cases, an applicant would be required to submit two reports to FDA in the first year after the effective date of the final rule (i.e., an initial report containing only information required under proposed Sec. 314.80(b)(2)(vii) or proposed Sec. 601.70 due within 6 months after the effective date and a complete annual report based on the product's anniversary date of U.S. approval due in the 7th to 12th month after the effective date). After the first year, applicants would only be required to submit one annual report to FDA each year.

There is little value in the requirement for a separate initial report for those NDAs with outstanding, pre FDAMA commitments within 6 months of the effective date of the final rule. The requirement should be fulfilled in the next Annual Report due for each product. This would also be more compatible with collation and publication of the planned Annual Federal Register Report.

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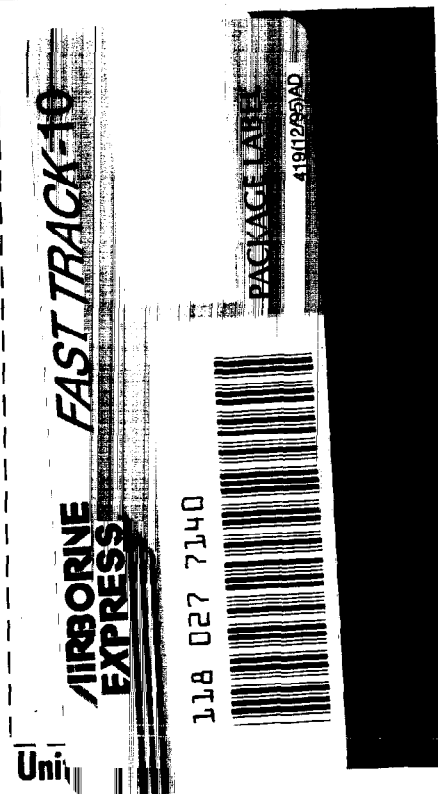
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